

REMARKS

This Response is to the Non-Final Office Action mailed July 23, 2003. Claims 1 to 73 were pending previously in this application. Claims 21 and 22 have been withdrawn previously due to a restriction requirement. Claims 1 to 20 and 23 to 73 stand rejected. In this Amendment, the specification is being amended in various places mainly to recite proper element numbers in connection with the drawings. The drawings are also being amended slightly to show correct element numbers. Claims 1, 12, 31, 36, 47, 51, 57, 60, 62 and 67 are being amended herein. No new matter has been introduced via the amendments to the specification, drawings or claims. It is believed that no fee is due in connection with this Amendment, however, please charge Deposit Account No. 02-1818 for any fees owed.

In the Office Action, the specification was objected to because alternative language was used in connection with elements numbers 72 and 74. Further, clarification with respect to the “guard plate” recited on page 20 was requested. Claims 13 to 30 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for claiming subject matter directed supposedly to non-elected species. Claims 1, 2, 4, 5, 9, 11 and 51 to 56 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,569,190 to D’Antonio (“*D’Antonio*”). Claims 1 to 6, 9 to 12, 31 to 40, 42, 43 and 45 to 73 were rejected under 35 U.S.C. §103(a) as being obviously in view of U.S. Patent No. 5,609,572 to Lang (“*Lang*”). Claims 7, 8, 41 and 44 were rejected under 35 U.S.C. §103(a) as being obvious in view of *Lang* and in further view of U.S. Patent No. 6,426,861 to Munshi (“*Munshi*”).

Regarding the objection of the use of both of the terms “flexible membranes” and “films” in connection with elements numbers 72 and 74, Applicants respectfully submit that the elements 72 and 74 do not have to either a flexible membrane or a film. That is precisely the reason that alternative language has been used. To the extent that flexible membranes and films are deemed to be the same thing, the point is moot. To the extent that flexible membranes and films are deemed to be separate apparatus, Applicants wish to include both interpretations when reciting elements numbers 72 and 74. Accordingly, the specification has not been amended in accordance with that objection and Applicants respectfully request reconsideration of same.

The specification has been amended at page 21 to clarify that the ground plate is plate 63 shown in Fig. 3, while the active plate is plate 65 shown in Fig. 3. Guard plate 67 is separate

from active plate 65 and ground plate 63 as seen in Fig. 3. Applicants respectfully submit that the amendments at page 21 adequately address the Patent Office's objection. Further, Applicants note that Figs. 1A to 1C and Fig 2 have been amended to show that the guard plate in those figures is indicated by element number 67 instead of element number 30, which is used elsewhere to indicate a low dielectric fluid, e.g., air. Fig. 2 is also amended to add amplifier element number 26, which is disclosed in the original specification, for example, at page 15, line 22.

Regarding the rejection of Claims 13 to 30 under 35 U.S.C. §112, Applicants respectfully traverse that rejection. Applicants elected in a previous paper the species of invention shown in Fig. 3. Fig. 3 illustrates a disposable cassette that operates with a medical fluid machine to pump medical fluid to a patient. The machine and cassette cooperate with a capacitive fluid volume sensor to monitor the volume of fluid pumped. Claims 13 to 30 are directed to that elected species. For example, Fig. 3 and its associated written disclosure describe each of the elements of Claim 13, including a plurality of capacitor plates, a dialysis receptacle and an electrical circuit. That same analysis holds true for Claim 14. The Patent Office does not specify why Claims 13 to 30 are treated differently than the non-rejected claims. Applicants cannot therefore address any specific rejection but instead state that each of the Claims 1 to 73, except for Claims 21 and 22 that refer to a pump piston, are supported by the disclosure in connection with Fig. 3. Accordingly, Applicants respectfully submit that Claims 13 to 30 are allowable at this time.

Regarding the rejection of the claims in view of *D'Antonio* and *Lang*, Applicants first wish to generally indicate the differences between those references and the present invention and then explain why the present claims are defined over those references alone or in combination. Beginning with *D'Antonio*, the pertinent portion of that reference is set forth in connection with Figs. 1, 2A, 2B and 4. The invention of *D'Antonio* is directed to a hypodermic fluid dispenser, which employs a jet injection system. *D'Antonio* uses a motor 221 that translates a ram 224 to compress a spring 227. The spring builds a compressive force against a plate 104, which is coupled to a bellows 100 and initially held in place so as not to compress bellows 100. Bellows 100 is filled with fluid. *D'Antonio* at column 11, line 14, indicates that the bellows is filled completely with fluid. In operation, spring 227, which has been previously held in a compressed

state, is released pushing plate 104 against bellows 110, compressing same, and forcing liquid through output port 109, as described at column 5, lines 15 to 24.

D'Antonio at the bottom of column 10 and continuing to column 11 describes in connection with its Fig. 4 an integrity test for its bellows. In general, the electrical circuit provides a frequency output that is produced by the collapsing bellows. The circuit tests that the frequency is within a specified operating range, indicating that the bellows was substantially full of fluid and therefore that a successful injection has taken place. A frequency detected to be outside the specified range shows "excessive voids, clots or an incorrect consistency". That is, *D'Antonio* looks for an indication of whether bellows 100 is full or not and homogeneous or not. At column 11, line 15, *D'Antonio* describes in an alternative embodiment that the ends of the bellows can form capacitor plates, wherein a variable capacitance of the fluid between the plates is used to determine a particular frequency F_b .

The present invention is structurally and functionally different than the alternative capacitance embodiment described in *D'Antonio*. In the present invention, the capacitor plates are spaced apart from one another in a fixed relationship with respect to each other as shown in Figs. 3 to 5. The capacitor plates are embedded in or connected to fixed volume chamber walls. A flexible fluid receptacle is housed in between the fixed capacitor plates. The fluid receptacle expands and contracts as fluid enters and leaves, respectively, from the receptacle. Thus, while there is a changing amount of fluid within the receptacle and therefore between the capacitor plates, there is also necessarily a changing amount of low dielectric fluid or air, which changes in inversely with the volume of fluid between the capacitor plates. The difference in dielectric constants between the therapy fluid and, for example, air is significant as described in the application. That difference is helpful to the operation of the volume sensor of the present invention.

The present invention therefore differs in at least two vital respects from *D'Antonio*. In one respect, the capacitor plates of the present invention are fixed with respect to each other, while the capacitor plates of *D'Antonio* move in relation to one another. Second, the sensor of the present invention senses the volume of fluid with respect to a changing of a volume of air, which the sensor and system employing same expect to see under normal operation. In *D'Antonio*, on the other hand, the integrity circuit expects to see only fluid under normal

operation and alarms when it sees air, a clot or other non-homogeneous entity. Those differences yield to the present invention structural and functional patentable features with respect to *D'Antonio*.

The claims of the present invention are also substantially different from *Lang*, both structurally and functionally. It is worth noting that as far as Applicants' representative can tell, *Lang* only mentions the word "capacitive" twice throughout the entire patent, namely, at Claims 14 and 16. In all other places, as best Applicants' representative can tell, *Lang* describes instead an inductive sensor, which magnetically senses the presence or absence of a ferromagnetic material, as for example called for in Claim 14. Fig. 3 of *Lang* is the most pertinent figure for purposes of this discussion. In Fig. 3, *Lang* places a single inductive position sensor 34 at the end of a plunger 33. Plunger 33 moves left to right to force fluid out of the pump or enable fluid to enter the pump. The single sensor 34 looks for a thrust plate 37, which includes a ferromagnetic material, as described at column 7, beginning at line 27. The sensor is used to indicate a distance between the plunger and the pump chamber 47. From that sensed distance, as column 7, line 27, indicates, the *Lang* system can determine whether a complete filling or evacuation has occurred as well as intermediate stages within the filling or evacuation.

The sensor of *Lang* is not sensing a changing dialectic relationship between fluids of different dielectric constants, such as dialysate and air, as called for by certain claims of the present invention. Further, *Lang*, like *D'Antonio*, does not show, teach or suggest the use of capacitor plates in a spaced apart, fixed relation to one another to determine a volume of medical fluid pumped as called for by other claims of the present invention.

The claims incorporate one or more of the above-discussed differences and are therefore distinguished over *D'Antonio*, *Lang* or a combination of same. Claims 1, 31, 47 and 60 each include, in effect, multiple capacitor plates spaced apart in a fixed relationship to one another or have other language indicating same. Neither *D'Antonio* nor *Lang* teaches or suggests such a feature. Accordingly, Claims 1, 31, 47 and 60 and the claims depending respectively from those claims are each novel, non-obvious and patentable in view *D'Antonio*, *Lang* or a combination of those references. Claim 62 specifies a method step of measuring a volume of dialysate that changes within a fixed volume chamber with a capacitor sensor coupled to the chamber. Neither *D'Antonio* nor *Lang* alone or together teach that feature. Accordingly, Claim 62 and Claims 63

to 66 that depend from Claim 62 are novel, non-obvious and patentably distinct over those references.

Other claims highlight the functional differences between the present invention and either *Lang* or *D'Antonio* alone or in combination. For example, Claims 12, 36, 51, 57 and 67 each highlight that the present invention in normal operation expects to see a volume of relatively low dielectric fluid, such as air, change as the volume of a medical fluid, such as dialysate, changes. *Lang* and *D'Antonio* do not disclose, teach or suggest such features. Applicants therefore respectfully submit that Claims 12, 36, 51, 57 and 67 as well as the claims depending respectively from those claims are novel, non-obvious and patentably distinct over *D'Antonio* and *Lang* alone or in combination.

It should be appreciated that the patentability of the independent claims over *Lang* and *D'Antonio* renders moot the obviousness rejection of Claims 7, 8, 41 and 44 depending from certain of those independent claims.

For the foregoing reasons, Applicants respectfully submit that the above-identified patent application is now in condition for allowance and earnestly solicit reconsideration of same.

Respectfully submitted,

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